REMARKS

Claims 7-11 are all the claims pending in the application.

Claim 7 has been editorially amended as suggested by the Examiner in the final rejection solely to clarify that the vector is administered in an effective amount. Claims 7, 8, and 11 have also been editorially amended to clarify that the vector contains the HGF "coding sequence." Finally Claim 7 has been amended to indicate that administration is at the "affected site," as supported at page 14, lines 4-6, for example.

No new matter is added.

Accordingly, entry of the Amendment is requested.

I. Advisory Action

In the Advisory Action, the Examiner stated that Applicant's reply has overcome the rejections under 35 U.S.C. §112, second paragraph, and the objection to Claim 7. However, the Examiner did not enter the amendment, asserting that adding the limitation that administration is at the "affected site" and clarifying that the promoter is operably linked to a HGF gene "coding sequence" raise possible issues of new matter.

The Examiner further stated that he did not consider the copy of Morishita et al., Hypertension, 2004, cited to support the enablement of intramuscular injections because the amendment had not been entered.

Accordingly, in order to have the amendment entered and fully considered, Applicant files this Request for Continued Examination.

II. Final Rejection

A. Objection of Drawings

The Examiner maintained the objection to Figures 12-15 because the figures contain two panels, but the description of the each of the figures appears to apply to only one panel.

The descriptions of Figures 12-15 have been amended to indicate that each panel shows a different magnification of the subject matter.

Thus, removal of this objection is requested, respectfully.

B. Objection to Claim 7

The Examiner suggested alternate wording for claim 7. The Examiner asserted that a literal reading of the original claim makes it appear that the HGF gene, rather than the vector, is administered in a therapeutically effective amount.

The Examiner is thanked for this suggestion, and the claims have been amended accordingly.

Based upon the Examiner's comments in the Advisory Action, this objection has been overcome. Accordingly, removal of this objection is requested, respectfully.

Also, the Examiner used "coding sequence" in place of "gene" in the proposed wording of the claim. Applicants believe that reference to the "coding sequence" is most accurate, and therefore Claim 7, as well as Claims 8 and 11 have been amended to use the more accurate language. This is different from the phrase "gene coding sequence" presented in the final rejection.

C. Rejection of Claims 7-11, 35 U.S.C. § 112, second paragraph

Claims 7-11 were rejected as indefinite because the term "peripheral muscle" in claim 7 is not defined in the specification.

Claim 7 has been amended to delete the term "peripheral muscle" and to instead recite that the administration is at the "affected site." This is supported at page 14, lines 4-6.

Based upon the Examiner's comments in the Advisory Action, this rejection has been overcome. Accordingly, removal of this rejection is requested, respectfully.

D. Rejection of claims 7-11, 35 U.S.C. § 112, first paragraph (for new matter)

Claims 7-11 were rejected under 35 U.S.C. § 112, first paragraph as lacking written description support in the specification, and, therefore, as adding new matter.

The Examiner asserted that there is no support for administering the vector to peripheral muscle. The Examiner further asserted that the specification only contemplates administration to target organs.

For the following reasons, Applicant asserts that the Examiner's position is incorrect.

While the specification highlights that administration can be directly to an organ, the specification also clearly contemplates administration to any affected site. For example, the specification at page 13, lines 25-28 state that the medicament may be administered through any route "appropriate for the disease to be treated." Further, at page 14, lines 4-6 state that administration can be directly to the objective site. An objective site can be more than a target organ. Further, administration to the affected site would be appropriate to treat insufficiency of peripheral circulation or peripheral angiostenosis.

In addition, Applicant previously submitted a copy of the article, Morishita et al., Hypertension, 2004; 44: 203-209, authored by the inventors of the present application. Although the article was published after the filing date of the present application, the article reports that intramuscular injection of naked HGF plasmid DNA to ischemic limbs of patients with peripheral arterial disease (i.e., insufficiency of peripheral circulation) achieved successful improvement of ischemic limbs. The Examiner is requested to consider the Morishita et al article in relation to this rejection.

In view of the above and the amendment to Claim 7, Applicant submits that the rejection is improper and/or overcome and removal thereof is requested, respectfully.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Susan J. Mack
Registration No. 30,951

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

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CUSTOMER NUMBER

Date: October 3, 2006